REMARKS

Claims 1-3, 5-20, and 31-32 are currently pending in the application. Reconsideration of the claims currently pending in the application is respectfully requested.

A. Response to the final office action dated July 28, 2003 is reproduced below to be included in the RCE:

I. Rejection under 35 U.S.C. §102 (b)

In paragraph 3 on page 2 of the Office Action, claims 1-8, 10-19, and 31 are rejected under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al. (U.S. Patent No. 4,778,461).

The Examiner notes that Pietsch, et al. teaches a medical device comprising a composite having an inorganic substrate (support ring) and a polymer (plastic) covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device (a heart valve whereby the support ring and the cusps are formed integrally as a result of the plastic skin, from which the cusps are formed, also enclosing the support ring, thus providing the form or shape of the device). The substrate (support ring) is made out of metal (stainless steel, titanium) or ceramics (column 3, lines 30-55). The polymer is crosslinked polydimethylsiloxane (silicone rubber), having high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness (column 4, lines 55-68 and column 5, lines 1-15). Crosslinked polyether-urethanes are

also taught to be suitable with a low Shore A hardness and a high breaking strength (column 4, lines 20-55).

The Examiner also states that since Pietsch, et al. teaches that the crosslinked silicone rubber (polydimethylsiloxane) has high fatigue strength in alternate bending, a high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400%, in the absence of a showing to the contrary, the Examiner has taken the position that the composite can be bent by at least 100 degrees while remaining elastic, by about 180 degrees without extending the component beyond its elastic limit, and by about 60 degrees for about 40 million cycles to about 400 million cycles without significant structural failure.

Applicants respectfully traverse the rejection.

Pietsch, et al. teach a heart valve shaped such that it does not have any points of attack for blood depositions, thrombi or scleroses. See col. 1, lines 44-46. The height of the support ring, including the commissure supports, is less than the total height of the heart valve prosthesis, preferably, amounting to 20-80%, particularly advantageously 40-60%, of the total height. See col. 1, lines 53-62. Preferably, the support ring and the cusps are formed integrally as a result of the plastic skin, from which the cusps are formed, also enclosing the support ring. See col. 3, lines 35-37. Also, in this preferred form, the support ring is made by injection-molding and consists of thermoplastic materials, and the cusps are formed by dipped coating. See col. 1, lines 63-68; col. 3, lines 32-40; col. 4, line 66 to col. 5, line 6; col. 5, lines 49-59; and col. 6, lines 3-19. Applicants submit that by this teaching, the support ring is part of the structure that provides the form of the device, and in this integral "all of one piece" device, the support

ring is also composed of only polymer, or glass fiber-containing polymer. See col. 3, lines 39-40 and 58-64. No inorganic substrate is present. If the support ring is metal or the other materials, other than polymers, set forth in col. 3, beginning on line 45, there is no mention in Pietsch that those materials should be covered with a polymer.

On the other hand, claim 1 of the present invention is directed to a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, and the polymer itself, and not the substrate, provides the form of the device. This is not shown in Pietsch. Applicants respectfully submit that Pietsch, et al. do not teach the subject matter of claim 1.

With regard to claim 10, the Pietsch patent does not disclose a composite that can be bent at least about 100 degrees without extending the material beyond its elastic limit, the subject matter of claim 10. In Pietsch, et al., the cusps are flexible, but they are not made of a substrate and polymer composite. See col. 3, lines 35-40. Also, as characterized by the Examiner, the support ring is taught to be deformable elastically. However, as taught in Pietsch, et al., deformable elastically is not the same as flexible, which is made clear by Pietsch in that the support ring "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissure) remains free and flexible." Col. 1, lines 60-68. While Pietsch, et al. also taught that metals and ceramics are used for the support ring, as also noted by the Examiner, nevertheless, there is no teaching that the support ring comprises a flexible composite of inorganic substrate and polymer, and that this composite can be bent, or to the degree noted in claim 10.

Therefore, while it is true that Pietsch, et al. teach that the polymer can be silicone rubber, having high fatigue strength in alternate bending as well as a high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400% (column 4, lines 55-68 and column 5, lines 1-15); or crosslinked polyether-urethanes with a low Shore A hardness of 60-80 (column 4, lines 20-55); or even a polyamide, these are preferred materials for fashioning the support ring. No inorganic substrate is disclosed or taught that, together with a polymer, forms a flexible composite that can be bent at least about 100 degrees without extending the composite beyond its elastic limit, the subject matter of claim 10. Applicants respectfully submit that Pietsch, et al. do not teach the subject matter of claim 10.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Pietsch, et al. do not teach every element of claims 1 and 10, and therefore fails to anticipate those claims.

Dependent claims 2-8, 11-19 and 31, which are dependent from their respective independent claims 1 and 10, were also rejected under 35 U.S.C. §102(b) as being unpatentable over Pietsch, et al. While Applicants do not acquiesce with the particular

rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 10. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-8, 11-19 and 31 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1-8, 10-19, and 31 under 35 U.S.C. §102 (b) as being anticipated by Pietsch, et al.

II. Rejection under 35 U.S.C. §103(a)

1. In paragraph 4 on page 3 of the Office Action, claim 20 is rejected under 35 U.S.C. §103(a) as being unpatentable over Pietsch, et al. in view of Sumimoto Electric Co. The Examiner noted that Pietsch, et al. teach the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device, but that Pietsch, et al. fails to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer. The Examiner then notes that Sumimoto Electric Co. teaches that coating by carbon or diamond of an artificial heart valve comprising polymer such as silicone polymer, polyurethane or PTFE gives the valve good antithrombosis property and good durability (abstract) thus providing the advantage and hence the motivation to coat the heart valve of Pietsch, et al. with carbon or diamond in order to provide antithrombogenicity and improved durability.

Applicants respectfully traverse the rejection.

Applicants submit that Pietsch, et al. do not teach the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device, as noted above. As admitted by the Examiner, Pietsch, et al. also fail to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer. While the Sumitomo abstract discloses a diamond-like carbon on a metal substrate for use as a heart valve prosthesis, Applicants further submit that Pietsch, et al. do not teach a composite with an inorganic substrate and a polymer at least partly covering the substrate, or that the composite of polymer and inorganic substrate is flexible and can be bent at least about 100 degrees without extending the material beyond its elastic limit, the subject matter of claim 10. In Pietsch, et al., the cusps are flexible, but they are not made of an inorganic substrate and polymer composite. See col. 3, lines 35-40. Also, Pietsch, et al. teaches that the support ring can be made of metals, ceramics, or thermoplastics. See col. 3, lines 45-56. While Pietsch, et al. recite modulus of elasticity, Pietsch, et al. do not teach that any of the materials for forming the support ring is made of a composite with an inorganic substrate and a polymer. A high modulus of elasticity means higher stiffness. A modulus of elasticity greater than 3000N/mm^2 is therefore not the same as flexibility, which is also made clear by Pietsch, et al. in that the support ring "supports only the lower part of the valve, whereas the upper part of the cusps and their joining zones (the commissure) remains free and flexible." See col. 3, lines 68 – col. 4, line 1, and col. 1, lines 60-68. Therefore, there is no teaching that the medical device of Pietsch, et al. comprises a flexible composite of inorganic substrate and polymer, and that this

composite can be bent, and to the degree noted in claim 10. The deficiency of Pietsch, et. al. is not supplied by the disclosure of a diamond-like coating over a metal in Sumitomo Electric, despite the Examiner's note that both Sumimoto Electric Co. and Pietsch, et al. are directed to an artificial heart valve. Therefore, Pietsch, et al. and Sumimoto Electric Co. do not teach or motivate one to arrive at the subject matter of claim 10.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations of claim 10 and there is simply no teaching or motivation to combine the references as proposed by the Examiner to arrive at the subject matter of claim 10. Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. §103 (a) as being obvious over Pietsch, et al. in view of Sumitomo Electric.

Claim 20 is dependent from clam 10. While Applicants do not acquiesce with the particular rejections to claim 20, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 10. Therefore, dependent claim 20 is also in condition for allowance.

Applicants respectfully request withdrawal of the rejection claim 20 under 35 U.S.C. § 103(a) as being anticipated by Pietsch, et al. in view of Sumimoto Electric Co.

2. In paragraph 5 on page 4 of the Office Action, claims 9 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pietsch, et al. in view of McGregor (U.S. Patent No. 4,627,836). Again the Examiner notes that Pietsch, et al. teach the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device. The Examiner admits that Pietsch, et al. fails to teach that the polymer is rigid, but asserts that MacGregor teaches a heart valve made from a combination of rigid polymeric material, metal or ceramic and carbon. The metal substrate is given as an example (column 3, lines 20-30 and column 4, lines 30-50). The thickness of the rigid porous rigid plastic coating is taught to be about 20 to 300 microns and the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength. The polymer may be attached by flowing into the metal substrate thus forming a barb or anchor (column 5, lines 5-50). The Examiner further asserts that because MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength, it would have been obvious to one of ordinary skill in the art to have used the combination of rigid polymer, metal or ceramic and carbon of MacGregor in the invention of Cromie in order to obtain a heart valve with the desired fatigue endurance limit.

Applicants respectfully traverse the rejections.

First, Applicants wish to point out that the Examiner in this rejection is using Pietsch, et al. in view of MacGregor, and not Cromie and MacGregor. Therefore, Applicants' comments below are directed to Pietsch, et al. in view of MacGregor.

Applicants also wish to direct the Examiner's attention to the argument made above concerning Pietsch, et al. and disagree that Pietsch, et al. teach the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device, and thus the only missing part is that Pietsch, et al. fails to teach that the polymer is rigid. As already discussed above, Pietsch, et al. do not teach the subject matter of claim 1. At the same time, though Pietsch, et al. and MacGregor are directed to an artificial heart valve, Applicants submit that the combination of teaching does not motivate one of ordinary skill in the art to arrive at the subject matter of claim 1.

MacGregor teaches a heart valve made from metal, or a combination of two or more materials such as rigid polymeric material, ceramic material and carbon. See col. 3, lines 21-25. The surface of the materials is porous. See col. 3, lines 26-42. Pore sizes are generally of 1 micron to 1000 microns, preferably, below about 20 microns. See col. 3, lines 43-46. The metal device maybe in the form of, or include, a rigid wholly porous system intended to engage blood and in which a network of interconnected pores extends throughout the body of the system. See col. 4, lines 6-11. Alternatively, the metal device may include a rigid composite of a dense coherent metallic substrate and a rigid metallic porous coating which consists of metallic particles joined to adjacent particles to form an interconnected network. See col. 4, lines 12-19. The suture or

sewing ring used in rigid metallic valves may be provided in the form of a flexible polymeric material having a porous surface. See col. 5, lines 22-27. Applicants submit that there is no motivation to combine teaching of Pietsch, et al. with that of MacGregor to arrive at claim 1, as the deficiency of Pietsch, et al. is not supplied by MacGregor. In fact, by the teaching cited above, MacGregor's composite has the form of the article. The cited art fails to meet the three criteria for establishing a *prima facie* case of obviousness noted above. Therefore, claim 1 is not obvious over Pietsch, et al. in view of MacGregor. MPEP § 2142.

Claims 9 and 32 are dependent from independent claim 1. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. Also, MacGregor mentions that the porous polymeric material may be provided with an outer surface of a conventional foam filled fabric covered suture ring, attached directly or through an intermediate solid substrate, which further motivates one of ordinary skill in the art away from the subject matter of these dependent claims. See col. 5, lines 30-34. Applicants respectfully traverse the rejection since the prior art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner. Therefore, claims 9 and 32 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 9 and 32 under 35 U.S.C. § 103(a) as being anticipated by Pietsch, et al. in view of McGregor.

B. Response to the Advisory Action

I. On page 2, paragraph 2 of the Advisory Action, the Examiner, in response to Applicants' argument that in the present application, the polymer itself and not the substrate provides the form of the device, contends that the embodiment of Fig. 3 in Pietsch, et al. shows a cross-sectional view of the heart valve whereby the cusp material 3 encloses the support ring 1, and that the boundary edge of the cusp has a rounded lobar thickened outline (column 8, lines 20-30), and thus the cusp 3 provides the form of the device. Further, the Examiner notes that since the cusp is made of flexible three-dimensionally crosslinked polymer (column 4, lines 20-3 0), and the support ring is made out of inorganic material (stainless steel, ceramics) (column 10, lines 10-15), it can be seen that the polymer (cusp) itself, and not the inorganic substrate, provides the form of the device.

Applicants respectfully traverse the argument.

As noted before, Pietsch, et al. teach a heart valve shaped such that it does not have any points of attack for blood depositions, thrombi or scleroses. See col. 1, lines 44-46. Fig. 3 of Pietsch, et al. shows a partial cross-section through the heart valve with a cusp 3, the support ring 1 and the groove 7 on the support ring. Pietsch, et al. note that preferably, the support ring and the cusps are formed integrally as a result of the plastic skin, from which the cusps are formed, also enclosing the support ring. See col 3, lines 35-37. While it is true that the cusp material encloses the support ring, the skin that also forms the cusps follows the contour of the support ring, including the groove. See Fig. 3. Thus, the support ring also provides the shape or form of the heart valve. See Fig. 3. The subject matter of claim 1 of the present invention is distinguished from this,

as claim 1 recites that the polymer itself, and not the substrate, provides the form of the device. Reconsideration is respectfully requested.

II. On page 2, paragraph 3 of the Advisory Action, the Examiner, in response to the Applicants' argument that the cusps of Pietsch, et al. are flexible, but are not made of a substrate and polymer composite, contends that in Fig.3 of Pietsch, et al., the cusp 3 extends all the way down, around and up over the support ring 1, which is a substrate and polymer composite.

Applicants respectfully traverse the Examiner's contention.

While it is true that the cusp 3 in Pietsch, et al. is made up of a polymeric material, which extends all the way down, around and up over the support ring 1, which is made of a substrate material, there is no teaching or disclosure in Pietsch, et al. that the support ring covered with the polymeric skin is flexible. Pietsch, et al. merely teach that the cusp is made of flexible material. See col. 2, lines 35-36, and lines 64-68. In fact, Pietsch, et al. specifically teach that the function of the support ring is to provide support to the flexible cusps to prevent the flapping over of the valve and to anchor the suture ring. See col. 3, lines 15-18. Thus, Pietsch, et al. clearly teach that where a part of the device is made up of a composite of an inorganic substrate and a flexible polymeric skin, that part that is formed with the composite is there to provide support and is clearly not flexible. Reconsideration is respectfully requested.

III. On page 2, paragraph 4, the Examiner, in response to Applicants' argument that Pietsch, et al. do not disclose a composite that can be bent at least about

100 degrees without extending the material beyond its elastic limit, cites that the disclosure of Pietsch, et al. includes a three-dimensionally crosslinked polydimethylsiloxane and contends that this material can be bent by at least 100 degrees while remaining elastic, and by about 180 degrees without extending beyond its elastic limit. The Examiner cites as evidence the teaching by Pietsch, et al. that the three-dimensionally crosslinked polydimethylsiloxane has high fatigue strength in alternate bending, high breaking strength of at least 8 N/mm at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % (column 4, lines 60-65). Further, the Examiner notes the elastic limit of a material as defined by a stress-strain curve included in the Advisory Action, wherein the deformation of the material is recoverable within the limit of the strain at the elastic limit. Finally, the Examiner notes that in Pietsch, et al., when a piece of the silicone rubber (crosslinked polydimethylsiloxane) is bent, or strained, it goes back to its original shape upon release of the bending force (strain) unless the force (or strain) at Applicants have failed to demonstrate that the bending force, or strain, is at least 8 N/mm.

Applicants respectfully traverse the Examiner's arguments.

Applicants agree that the three-dimensionally crosslinked polydimethylsiloxane has high fatigue strength in alternate bending, high breaking strength of at least 8 N/mm at a low Shore A hardness of 25-35, and an elongation at break of more than 400 %, as noted in Pietsch, et al. (column 4, lines 60-65). However, Applicants wish to point out that these properties described are those of the polymeric skin alone, and not of a composite of polymeric skin and substrate. There is no teaching or motivation in Pietsch, et al. of a composite of polymeric skin and substrate possessing these

properties. Since the subject matter of claim 10 of the present invention is related to a composite having bending properties, and Pietsch, et al. specifically teach that the function of the support ring is to provide support to the flexible cusps to prevent the flapping over of the valve and to anchor the suture ring, Pietsch, et al. clearly teach that where a part of the device is made up of a composite of an inorganic substrate and flexible polymeric skin, that part formed with the composite is there to provide support and is clearly not flexible. See col. 3, lines 15-18. Applicants submit that Pietsch, et al. is distinguished. Reconsideration is respectfully requested.

IV. On page 4, paragraph 5, in Response to Applicants' argument that Pietsch, et al. do not teach that the support ring comprises a flexible composite of inorganic substrate and polymer that can be bent, or to the degree noted in claim 10, the Examiner contends that a support ring comprising a flexible composite of inorganic substrate and polymer is not presently claimed, but that a "medical device" is presently claimed which comprises a composite comprising an inorganic substrate and a polymer member covering at least a portion of the substrate. The Examiner further notes that the term "comprising" means that the composite can form only part of the medical device. Finally, the Examiner contends that Fig. 3 of Pietsch, et al. does indeed show a support ring 1 which comprises a flexible composite of inorganic substrate 1 and polymer cusp material 3.

Applicants respectfully traverse the Examiner's contention.

Applicants agree that the present claim is not directed to a support ring, but a medical device. Applicants also agree that the support ring of Pietsch, et al. has a

composite of inorganic substrate and polymer. However, there is no teaching or motivation in Pietsch, et al. that where the composite is used in the medical device, for example, in the support ring, that the composite or the support ring is flexible. In fact, Pietsch, et al. specifically teach away from a flexible composite when they teach that the function of the support ring is to provide support to the flexible cusps to prevent the flapping over of the valve and to anchor the suture ring. See col. 3, lines 15-18. Thus, Pietsch, et al. clearly teach that where a part of the device is made up of a composite of an inorganic substrate and flexible polymeric skin, that part formed with the composite is there to provide support and is clearly not flexible. This is in contrast to the subject matter of claim 10, wherein the flexible composite component can be bent. Reconsideration is respectfully requested.

V. On page 4, paragraph 6 of the Advisory Action, the Examiner, in response to Applicants' argument that MacGregor's composite has the form of the article, notes that Applicants fail to specify in what way this pertains to the present claim language.

Applicants respectfully submit that Pietsch, et al. does not teach or motivate the subject matter of claim 1, as discussed above, as the plastic skin follows the contour of the underlying support ring, the support ring therefore contributes to the shape or form of the valve. At the same time, as noted before, MacGregor teaches a heart valve made from metal, or a combination of two or more materials such as rigid polymeric material, ceramic material and carbon. See col. 3, lines 21-25. The surface of the materials is porous. See col. 3, lines 26-42. Pore sizes are generally of 1 micron to 1000 microns, preferably, below about 20 microns. See col. 3, lines 43-46. The metal device maybe in

the form of, or include, a rigid wholly porous system intended to engage blood and in which a network of interconnected pores extends throughout the body of the system. See col. 4, lines 6-11. Alternatively, the metal device may include a rigid composite of a dense coherent metallic substrate and a rigid metallic porous coating which consists of metallic particles joined to adjacent particles to form an interconnected network. See col. 4, lines 12-19. The suture or sewing ring used in rigid metallic valves may be provided in the form of a flexible polymeric material having a porous surface. See col. 5, lines 22-27. Applicants submit that there is no motivation to combine the teaching of Pietsch, et al. with that of MacGregor to arrive at claim 1, as the deficiency of Pietsch, et al. is not supplied by MacGregor, because if a combination of two or more materials is used in MacGregor, it is usually of a flexible or rigid solid and/or porous plastic material coatings on rigid metal coatings or other heart valve components, by pressure molding a polymer to the metal coating. See col. 5, lines 44-48. This pressure molded composite is then formed into the shape of, for example, a pacemaker electrode. See col. 5, lines 63-68. Thus, the composite in MacGregor is formed into the shape of the device, unlike the subject matter of claim 1, where the polymer alone provides the shape or form of the device. Reconsideration is respectfully requested.

VI. On page 4, paragraph 7, the Examiner, in response to Applicants' argument that there is no motivation to combine MacGregor with Pietsch, et al, notes that MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength anchor (column 5, lines 5-20), which provides the advantage and thus the motivation to have used the combination of rigid polymer, metal

or ceramic and carbon of MacGregor in the invention of Pietsch, et al. in order to obtain a heart valve with the desired fatigue endurance limit.

Applicants respectfully traverse the Examiner's argument.

Applicants agree that MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength anchor (column 5, lines 5-20). However, since the subject matter of Applicants' claim 1, to which this rejection is directed, is related to a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device, is not taught or motivated in Pietsch, et al., Applicants fail to see how a reference that recites a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength anchor can supply the deficiency of Pietsch, et al. In addition, even if the references are combinable, the combined teaching of Pietsch, et al. and MacGregor still does not render the subject matter of claim 1 obvious, since MacGregor fails to supply the deficiency of Pietsch, et al.'s teaching, that the polymer provides the form or shape of the device. Reconsideration is respectfully requested.

I. Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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